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EXAMINER	
RINES, ROBERT D	

ART UNIT	PAPER NUMBER
3626	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/089,761	ANDERSON ET AL.	
	Examiner	Art Unit	
	R. DAVID RINES	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2007 and 21 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-24,26-56 and 62-72* is/are pending in the application.

4a) Of the above claim(s) *62-66 and 68-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-24,26-56 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/28/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

[1] Applicant's election without traverse of claims 1-4, 6-24, 26-56, and 67 in the reply filed 21 December 2007 is entered (Election of Group I: claims drawn to a patient medicament delivery system under the control of the patient that is arranged to collect data, classified in class 705, subclass 3, as specified in the Requirement for Restriction mailed 21 November 2007).

Notice to Applicant

[2] This communication is in response to the amendment filed 15 August 2007 and Applicant's election filed 21 December 2007. The IDS filed 28 February 2008 has been entered and considered. As per the amendment filed 15 August 2007, claims 1 and 47 have been amended. Claims 5, 25, and 57-61 have been cancelled. As per Applicant's election filed 21 December 2007, claims 62-66 and 68-72 have been withdrawn from consideration. Claims 1-4, 6-24, 26-56 and 62-72 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] Claims 1-4, 6-24, and 26-56 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As per the amendment filed 15 August 2007, Applicant has amended claims 1 and 47 to recite…"wherein said patient electronic data collection….. forms part of a medicament delivery system that is under the control of the patient and that is arranged to collect data when the patient uses the medicament delivery system.". From the amended limitation it is unclear which system elements are under the "control of the patient". More specifically, it is unclear if simply a drug delivery device, such as a pill box or an IV pump is "under the control of the patient" or if the system in its entirety including the specific "arrangement" is "under control of the patient". For purposes of applying art, Examiner assumes Applicant assumes that the delivery system, as opposed to the over system and its associated "arrangement" is "under the control of the patient". Examiner has addressed this limitation accordingly below however, appropriate clarification is requested.

Claims 2-4, 6-24, 26-46, and 48-56, by virtue of their dependence on claims 1 and 47, and when analyzed in the same manner described with respect to claims 1 and 47, also fail to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Therefore, claims 2-4, 6-24, and 48-56 are rejected under 35 U.S.C. 112, second paragraph, as well.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[4] Claims 1-7, 9-15, 17, 18, 20-34, 47-56, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaHuerga (United States Patent #6,408,330) in view of Yarin et al. (United States Patent #6,294,999).

As per claim 1, DeLaHeurga discloses a system for the remote assessment of a patient's medical condition comprising: a network computer system having specifiable network addresses (DeLaHuerga; col. 10, lines 6-35 and col. 17, lines 38-55); remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition (DeLaHuerga; col. 9, lines 5-24 and col. 19, lines 14-55 *see "ICD"); a communicator for wirelessly communicating with an entry point to said network computer system to enable transfer of said data to the network computer system, wherein the data includes a patient identifier(DeLaHuerga; col. 18, lines 45-59 and col. 34, lines 53-67 *see "patient identification number"); and a secure access gateway permitting access to the data on the network computer system in response to a user authorization command (DeLaHuerga; col. 19, lines 44-56, col. 23, lines 59-67, and col. 24, lines 1-37 *entry of a "password" is considered to be a form of "a user authorization command")

As per the 8/15/07 amendment, claim 1 has been amended to additionally recite "wherein said patient electronic data collection system forms part of a medicament delivery system that is under the control of the patient and that is arranged to collect data when the patient uses the medicament delivery system."

As per this element, DeLaHuerga discloses "wherein said patient data collection system forms a part of a medicament delivery system that is arranged to collect data when the patient uses the medicament delivery system (DeLaHuerga; col. 9, lines 15-40 *see "IV pump" and "medical container").

While DeLaHuerga discloses multiple "smart devices" for the administering medication to a patient and further DeLaHuerga discloses automated reporting of drug administering information to the "information collection device" (DeLaHuerga; col. 9, lines 14-40), DeLaHuerga appears to be focused on physician directed drug administration and thus fails to specifically indicate that the drug delivery device is "under the control" of the patient.

However, as evidenced by Yarin et al., it is well known in the remote healthcare/patient monitoring art issue a smart device such as a medicine tray that reports usage data to a central storage system via a computer network, to a patient. (Yarin et al.; Abstract and col. 10, lines 53-67 and col. 11, lines 1-27). Accordingly, Yarin et al. discloses a "medicament delivery system that is under the control of the patient and that is arranged to collect data when the patient uses the medicament delivery system".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of DeLaHuerga with those provided by Yarin et al. Such combination would have provided for a system-enabled method that includes an "information collection device" that gathers data related to the administration of a drug to a patient from multiple "smart devices" including IV pumps and electronic medicament containers (DeLaHuerga; col. 9, lines 5-40). Further, such a system-enabled method would have employed well known smart devices, such as a "Smart Tray", that are designed for patient use and report usage information to a third parties via a computer network (Yarin et al.; Abstract). The

motivation to combine the teachings would have been to facilitate effective self-management of medication treatment by patients (Yarin et al.; col. 3, lines 20-25).

As per claim 2, DeLaHuerga discloses a system wherein said patient electronic data collection system forms part of a patient monitoring system which collects data relevant to the patient's medical condition on a regular basis (DeLaHuerga; col. 9, lines 5-24 and col. 19, lines 14-55 *see "ICD").

As per claim 3, DeLaHuerga discloses a system wherein the patient electronic data collection systems forms part of a compliance monitoring system which collects data relevant to the patient's medical condition on a continuous basis (DeLaHuerga, col. 9, lines 15-23, 55-64).

As per claim 4, DeLaHeurga discloses a system wherein said patient monitoring system forms part of a compliance monitoring system arranged to monitor patient compliance with a particular treatment regime, (DeLaHeurga, col. 1, lines 35-47).

Claim 5 has been cancelled.

As per claim 6, DeLaHeurga discloses a system wherein the medicament delivery system provides respirable delivery of medicament to the patient (DeLaHeurga, col. 17, lines 36-55).

As per claim 7, DeLaHeurga discloses a system wherein the medicament delivery system provides injectable delivery of medicament to the patient (DeLaHeurga, col. 17, lines 36-55).

As per claim 9, DeLaHuerga discloses a system wherein data is communicable between the patient electronic data collection system and the network computer system in encrypted form (DeLaHeurga, col. 15, lines 26-35).

As per claim 10, DeLaHuerga discloses a system wherein data is continuously communicable between the patient electronic data collection system and the network computer system (DeLaHuerga, col. 9, lines 15-23, 55-64).

As per claim 11, DeLaHuerga discloses a system wherein the data is communicable in packet form between the patient electronic data collection system and the network computer system (DeLaHeurga, col. 10, lines 6-12).

As per claim 12, DeLaHuerga discloses a system wherein the secure access gateway is password protected (DeLaHuerga; col. 19, lines 44-56, col. 23, lines 59-67, and col. 24, lines 1-37.

As per claim 13, DeLaHuerga discloses a system wherein the secure access gateway enables different levels of access authorization to the data to be assigned to different authorized users (DeLaHeurga, col. 32, lines 59-66).

As per claim 14, DeLaHeurga discloses a system wherein the authorized users are selected from the group consisting of the patient, a healthcare professional, a pharmacist, an emergency assistance provider, a research professional, a database manager and any combinations thereof (DeLaHeurga, col. 32, lines 59-66).

As per claim 15, DeLaHeurga discloses a system wherein information from a patient-remote datasource is made available to the network computer system (DeLaHeurga, col. 33, lines 1-5).

As per claim 17, DeLaHeurga discloses a system wherein the patient-remote datasource comprises a database of prescribable medicaments (DeLaHeurga, col. 46, line 65-col. 47, line 25).

As per claim 18, DeLaHeurga discloses a system wherein the patient electronic data collection system further comprises a patient electronic data management system comprising a memory for storage of data, (DeLaHeurga, col. 17, line 66-col. 18, line 1);a microprocessor for performing operations on said data, (DeLaHeurga, col. 18, lines 10-20); and a transmitter for transmitting a signal relating to the data or the Outcome of an operation on the data, (DeLaHeurgal col. 2, lines 48-55).

As per claim 20, DeLaHeurga discloses a system wherein the communicator enables two-way transfer of data between the network computer system and the patient electronic data management system, (DeLaHeurga, col. 18, lines 15,16).

As per claim 21, DeLaHuerga discloses a system additionally comprising an authorized user data communicator comprising an authorized user electronic data management system comprising a memory for storage of data; a microprocessor for performing operations on said data (DeLaHuerga; col. 18, lines 10-36); and a transmitter for transmitting a signal relating to the data or the outcome of an operation on the data (DeLaHuerga; col. 9, lines 15-40); and a communicator for wirelessly communicating with an entrypoint to a network computer system to enable communication of data between the network computer system and the authorized user electronic data management system (DeLaHuerga; col. 12, lines 42-65, col. 18, lines 45-59 and col. 34, lines 53-67).

As per claim 22, DeLaHuerga fails to explicitly recite prescription information.

However, Yarin et al. disclose a system for the remote assessment of a patient's medical condition and remote prescription therefor comprising a first authorized user data communicator capable of communicating a prescription authorization command to the to the network computer system (Yarin et al; col. 11, lines 10-27 *Examiner considers the physician to be a "first user"); and a second authorized user data communicator capable of receiving a prescription authorization command from the network computer system (Yarin et al; col. 11, lines 10-27 *Examiner considers the patient to be a "second user").

As per claim 23, DeLaHeurga discloses a system wherein any communicator employs radiofrequency or optical signals (DeLaHeurga, col. 39, lines 47-51).

As per claim 24, DeLaHuerga discloses a system wherein any communicator communicates directly with the network computer system (DeLaHuerga; col. 17, lines 38-67 and col. 18, lines 1-20).

Claim 25 has been cancelled.

As per claim 26, DeLaHuerga discloses a system wherein the communicator communicates with the network computer system via a second communications device having telecommunications capability (DeLaHuerga; col. 17, lines 38-67 and col. 18, lines 1-20).

As per claim 27, DeLaHeurga discloses a system wherein the telecommunications device comprises a cellular phone or pager (DeLaHeurga, col. 54, lines 39-41).

As per claim 28, DeLaHeurga discloses a system wherein the communicator communicates with the second communications device using spread spectrum radiofrequency signals (DeLaHeurga, col. 18, lines 45-59).

As per claim 29, DeLaHeurga discloses a system wherein the network computer system comprises a public access network computer system (DeLaHeurga, col. 17, lines 55-65).

As per claim 30, DeLaHeurga discloses a system wherein the network computer system comprises a private access network computer system (DeLaHeurga, col. 17, lines 55-65).

As per claim 31, DeLaHeurga discloses a system wherein the patient-specific network address is selected from the group consisting of a web-site address, an e-mail address and a file transfer protocol address (DeLaHeurga, col. 18, lines 37-44).

As per claim 32, DeLaHuerga discloses a system wherein the patient electronic data management system additionally comprises a data input system for patient input of data to the electronic data management system (DeLaHuerga; col. 20, lines 47-63 *see patient "bracelet").

As per claim 33, DeLaHeurga discloses a system wherein said data input system comprises a man machine interface selected from a keypad, graphical user interface (GUI), voice recognition interface or biometrics interface (DeLaHeurga, col. 31, lines (24-26).

As per claim 34, DeLaHeurga discloses a system additionally comprising a display for display of data from the patient electronic data management system to the patient, (DeLaHeurga, col. 17, lines 36-54).

Regarding claims 2-4, 6-7, 9-15, 17-18, 20-24, and 25-34, the obviousness and motivation to combine as discussed with regard to claim 1 above are applicable to claims 2-4, 6-7, 9-15, 17-18,

20-24, and 25-34 and are herein incorporated by reference.

As per (as amended 8/15/07) claim 47, DeLaHeurga discloses a method comprising locally collecting data relevant to the patient's medical condition in electronic form (DeLaHuerga; col. 9, lines 5-24 and col. 19, lines 14-55 *see "ICD"); wirelessly communicating with an entrypoint to a remote network computer system to enable transfer of said data to said remote network computer system (DeLaHuerga, col. 7, lines 55-60); and permitting authorized user access to the data on the remote network computer system via a secure access gateway (DeLaHuerga, col. 14, lines 15-27).

As per the 8/15/07 amendment, claim 47 has been amended to additionally recite "wherein said step of collecting data utilizes a patient electronic data collection system that forms part of a medicament delivery system that is under the control of the patient and that is arranged such that the data is collected when the patient uses the medicament delivery system".

As per this element, DeLaHuerga discloses "wherein said patient data collection system forms a part of a medicament delivery system that is arranged to collect data when the patient uses the medicament delivery system (DeLaHuerga; col. 9, lines 15-40 *see "IV pump" and "medical container").

While DeLaHuerga discloses multiple "smart devices" for the administering medication to a patient and further DeLaHuerga discloses automated reporting of drug administering information

to the "information collection device" (DeLaHuerga; col. 9, lines 14-40), DeLaHuerga appears to be focused on physician directed drug administration and thus fails to specifically indicate that the drug delivery device is "under the control" of the patient.

However, as evidenced by Yarin et al., it is well known in the remote healthcare/patient monitoring art issue a smart device such as a medicine tray that reports usage data to a central storage system via a computer network, to a patient. (Yarin et al.; Abstract and col. 10, lines 53-67 and col. 11, lines 1-27). Accordingly, Yarin et al. discloses a "medicament delivery system that is under the control of the patient and that is arranged to collect data when the patient uses the medicament delivery system".

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of DeLaHuerga with those provided by Yarin et al. Such combination would have provided for a system-enabled method that includes an "information collection device" that gathers data related to the administration of a drug to a patient from multiple "smart devices" including IV pumps and electronic medicament containers (DeLaHuerga; col. 9, lines 5-40). Further, such a system-enabled method would have employed well known smart devices, such as a "Smart Tray", that are designed for patient use and report usage information to a third parties via a computer network (Yarin et al.; Abstract). The motivation to combine the teachings would have been to facilitate effective self-management of medication treatment by patients (Yarin et al.; col. 3, lines 20-25).

As per claim 48, DeLaHeurga discloses a method comprising collecting the data on a regular basis (DeLaHuerga, col. 9, lines 15-23, 55-64).

As per claim 49, DeLaHeurga discloses a method comprising collecting the data on a continuous basis (DeLaHuerga, col. 9, lines 15-23, 55-64).

As per claim 50, DeLaHeurga discloses a method comprising wirelessly communicating the data in encrypted form (DeLaHeurga, col. 15, lines 26-35).

As per claim 51, DeLaHeurga discloses a method wherein the data is continuously communicable (DeLaHuerga, col. 9, lines 15-23, 55-64).

As per claim 52, DeLaHeurga discloses a method wherein the data is communicable in packet form (DeLaHeurga, col. 10, lines 6-12).

As per claim 53, DeLaHeurga discloses a method comprising permitting different levels of access to the data to different authorized users (DeLaHeurga, col. 32, lines 59-66).

As per claim 54, DeLaHuerga discloses a method comprising a first authorized user communicating a prescription authorization command to the network computer system (DeLaHeurga, col. 46, line 65-col. 47, line 25); a second authorized user receiving said prescription authorization command from the network computer system (DeLaHuerga; col. 46,

line 65-col. 47, line 25); said second authorized user preparing the prescription based on the prescription authorization (DeLaHuerga; col. 46, line 65-col. 47, line 25).

As per claim 55, DeLaHeurga discloses a method for remotely assessing a patient's condition and remotely prescribing therefor additionally comprising:a first authorized user communicating a prescription authorization command to a pharmacy network computer system (DeLaHeurga, col. 46, line 65-col. 47, line 25); a second authorized user receiving said prescription authorization command from the pharmacy network computer system (DeLaHeurga, col. 46, line 65-co1.47, line 25); and said second authorized user preparing the prescription for the patient based on the prescription authorization (DeLaHeurga, col. 46, line 65-col. 47, line 25),wherein the pharmacy network computer system is arranged for communication with the network computer system (DeLaHeurga, col. 46, line 65-col. 47, line 25).

As per claim 56, DeLaHeurga discloses a method wherein the first authorized user communicates the prescription authorization in response to a 'update prescription' alerting signal visible at the patient-specific network address, (DelaHeurga, col. 4, line 52-col. 5, line 4).

Regarding claims 48-56, the obviousness and motivation to combine as discussed with regard to claim 47 above are applicable to claims 48-56 and are herein incorporated by reference.

Claims 57-61 have been cancelled.

Claims 62-66 have been withdrawn from consideration.

As per (newly added) claim 67, a system for the remote assessment of a patient's medical condition comprising a network computer system having specifiable network addresses (DeLaHuerga; col. 10, lines 6-35 and col. 17, lines 38-55); remote from said network computer system, a patient electronic data collection system for locally collecting data relevant to the patient's medical condition (DeLaHuerga; col. 9, lines 5-24 and col. 19, lines 14-55 *see "ICD"); a communicator for wirelessly communicating with an entry point to said network computer system to enable transfer of said data to the network computer system, wherein the data includes a patient identifier(DeLaHuerga; col. 18, lines 45-59 and col. 34, lines 53-67 *see "patient identification number"); and a secure access gateway permitting access to the data on the network computer system in response to a user authorization command (DeLaHuerga; col. 19, lines 44-56, col. 23, lines 59-67, and col. 24, lines 1-37 *entry of a "password" is considered to be a form of "a user authorization command"); wherein the patient electronic data collection system forms part of a medicament delivery system and is arranged to collect data when the patient uses the medicament delivery system (DeLaHuerga; col. 9, lines 14-40).

While DeLaHuerga discloses multiple smart devices for administering drugs to a patient and the devices are controlled via a network (DeLaHuerga; col.9, lines 15-40), DeLaHuerga fails to exemplify a change to the patient's prescription via the network.

However, as evidenced by Yarin et al., it is well known in the remote healthcare/patient monitoring to utilized networked communications to modify or change a patient's dosages or prescription via communication with the smart device via the network (Yarin et al.; col. 11, lines 11-26). Accordingly, Yarin et al. disclose a system-enabled method "wherein a patient-remote datasource is made available to the network computer system such that information relating to changes to prescription details is transferable thereto." (Yarin et al.; col. 11, lines 11-26).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of DeLaHuerga with those provided by Yarin et al. Such combination would have provided for a system-enabled method that includes an "information collection device" that gathers data related to the administration of a drug to a patient from multiple "smart devices" including IV pumps and electronic medicament containers (DeLaHuerga; col. 9, lines 5-40). Further, such a system-enabled method would have employed well known smart devices, such as a "Smart Tray", that are designed for patient use and report usage information to a third parties via a computer network (Yarin et al.; Abstract). The motivation to combine the teachings would have been to facilitate effective self-management of medication treatment by patients (Yarin et al.; col. 3, lines 20-25).

Claims 68-72 have been withdrawn from consideration.

[5] Claims 35-46 are rejected under 35 U.S.C. 103(a) as being anticipated by DeLaHuerga, (U.S. 6,408,330), in view of Admitted Prior Art.

As per claims 35-46, as per the response filed 15 August 2007 and the election filed 21 December 2007, Applicant has not traversed Examiner's Official Notice taken in the Office Action mailed 7 March 2007. Accordingly, the below noted limitations previously addressed under Examiner's Official Notice are hereinafter considered Admitted Prior Art.

As per claim 35, DeLaHeurga fails to disclose a system for the remote assessment of a patient's respiratory condition additionally comprising a sensor, which senses the breath of a user, wherein the sensor communicates breath data to the patient electronic data collection system. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 36, DeLaHeurga fails to disclose a system wherein said sensor comprises a breath-movable element which is movable in response to the breath of a patient. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 37, DeLaHeurga fails to disclose a system wherein said breath- movable element is selected from the group consisting of a vane, a sail, a piston and an impeller. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54)..

As per claim 38, DeLaHeurga fails to disclose a system wherein the sensor comprises a pressure sensor for sensing the pressure profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 39, DeLaHeurga fails to disclose a system wherein the sensor comprises an airflow sensor for sensing the airflow profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 40, DeLaHeurga fails to disclose a system wherein the sensor comprises a temperature sensor for sensing the temperature profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote

patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 41, DeLaHeurga fails to disclose a system wherein the sensor comprises a moisture sensor for sensing the moisture profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumpsl and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga, (DeLaHeurga, col. 17, lines 36-54).

As per claim 42, DeLaHeurga fails to disclose a system wherein the sensor comprises a gas sensor for sensing the oxygen or carbon dioxide profile associated with the breath of a user. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per Claim 43, DeLaHeurga fails to disclose a system wherein said breath data includes breath cycle data. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 44, DeLaHeurga fails to disclose a System wherein said breath data includes peak flow data. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 45, DeLaHeurga fails to disclose a system for the remote assessment of a patient's cardiovascular condition additionally comprising a sensor which senses the cardiovascular activity of a patient, wherein the sensor communicates cardiovascular data to the electronic data collection system. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

As per claim 46, DeLaHeurga fails to disclose a system wherein said sensor measures the blood pressure of the patient. However, such a feature is well-known in the art of ventilators, IV pumps, and other remote patient monitoring and treatment devices and therefore would have been obvious to incorporate into DeLaHeurga (DeLaHeurga, col. 17, lines 36-54).

[7] **Claims 8, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeLaHeurga, (U.S. 6,408,330), in view of Thompson, (U.S. 6,083,248).**

As per claim 8, DeLaHeurga fails to disclose a system, wherein the medicament delivery system is an implant in the body of the patient. However, such a feature is well- known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art a t the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

As per claim 16, DeLaHeurga fails to disclose a system wherein the patient- remote datasource comprises data relating to ambient environmental conditions.

However, such a feature is well-known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art a t the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of

the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

As per claim 19, DeLaHeurga fails to disclose a system wherein said patient electronic data management system additionally comprises a geographic positioning system. However, such a feature is well-known in the art as evidenced by Thompson, (Thompson, Abstract).

It would have been obvious to one of ordinary skill in the art a t the time of the invention to combine DeLaHeurga and Thompson. The motivation would have been to enhance the ability of the medical system to find patients and get reports on patient and medical device status, and update medical device programming, (Thompson, Abstract).

Response to Remarks/Amendment

[8] Applicant's arguments filed 15 August 2007 have been fully considered by the Examiner and are considered moot in view of newly added grounds of rejection.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 15 August 2007 amendment/21 December 2007 election, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of DeLaHuerga, Admitted Prior Art, Thompson, and newly added reference Yarin et al., based on the logic and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed 7 March 2007), and incorporated by reference herein.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. DAVID RINES whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. DAVID RINES/
Examiner, Art Unit 3626
12/ May 2008

/C Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626